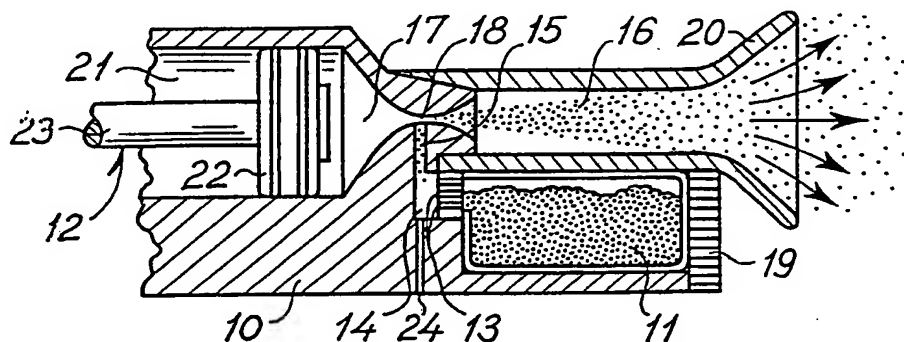




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 13/00, 15/00	A1	(11) International Publication Number: WO 90/07351 (43) International Publication Date: 12 July 1990 (12.07.90)
(21) International Application Number: PCT/DK90/00005 (22) International Filing Date: 8 January 1990 (08.01.90) (30) Priority data: 65/89 6 January 1989 (06.01.89) DK 659/89 10 February 1989 (10.02.89) DK 4791/89 28 September 1989 (28.09.89) DK (71)(72) Applicants and Inventors: SCHENK, Hans, Gernot [DK/DK]; Hovborgvej 11, Lindknud, DK-6650 Brørup (DK). PEDERSEN, Søren [DK/DK]; Vangen 17, DK-6000 Kolding (DK). (74) Agent: PLOUGMANN & VINGTOFT; Sankt Annæ Plads 11, DK-1250 Copenhagen K (DK).		(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report.</i>

(54) Title: AN ORAL INHALER**(57) Abstract**

An oral inhaler for use in inhaling a powdered or particulate medical product comprises a chamber (14) for containing the medical product, a mixing chamber (16), a gas flow passage (17) connected to the mixing chamber, and a pressure gas source or pumping device (40) for briefly providing in the gas flow passage a vigorous gas flow directed towards the mixing chamber. In order to obtain a high velocity of the gas flow, the gas flow passage (17) has nozzle-like restriction (18). The product chamber (14) is communicating with the gas flow passage (17) at the restriction (18) or adjacent thereto so as to draw product from the product chamber into the gas flow by ejector effect, whereby the product is disintegrated in small respirable particles, which are thoroughly mixed with the gas flow. A product reservoir (11) may be provided for containing a product supply sufficient for several inhalation procedures. The medical product may, for example, be transferred from a product reservoir to product chambers or metering chambers (14), which are defined in a rotatable cylinder or drum (38). The pressure gas source may be a pumping device, such as a piston pump. However, the pumping device preferably comprises a pumping chamber having a springy, diaphragm-like wall part (40).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	HU	Hungary	NO	Norway
BJ	Benin	IT	Italy	RO	Romania
BR	Brazil	JP	Japan	SD	Sudan
CA	Canada	KP	Democratic People's Republic of Korea	SE	Sweden
CF	Central African Republic	KR	Republic of Korea	SN	Senegal
CG	Congo	LI	Licchtenstein	SU	Soviet Union
CH	Switzerland	LK	Sri Lanka	TD	Chad
CM	Cameroon	LU	Luxembourg	TG	Togo
DE	Germany, Federal Republic of	MC	Monaco	US	United States of America
DK	Denmark				

AN ORAL INHALER

The present invention relates to an oral inhaler for use in inhaling a powdered or particulate medical product.

Medical treatment of bronchial asthma and other diseases may be performed in different ways. The most effective manner of administration is to let the patient inhale the medical product directly into the bronchial tubes of the lungs. However, the medical product particles cannot penetrate sufficiently deeply into the bronchial tubes unless they are very small. Thus, only particles having a diameter of less than 7 μm have a chance to penetrate completely into the bronchial tubes. Particles having such a small size that they may be deposited in the bronchial tree by aspiration are called "respirable particles".

Up till now it has been attempted to make medical product particles respirable in two principally different manners:

In the first manner, an aerosol spray is discharged from a small aerosol container in which the medical product particles having a size of about 3 μm are dispersed by means of Freon under high pressure (400 kPa). In order to prevent the particles from lumping together in the Freon atmosphere it is necessary to add different surface tension reducing agents and lubricants, which for some patients may give rise to side effects when inhaled. Due to the high pressure within the aerosol container a metered amount of the medical product is discharged therefrom at a rather high velocity (100 km/-hour). For that reason it is rather difficult for many patients to inhale the medical product from a usual aerosol container in a correct manner. Thus, even after having been instructed by a doctor or a nurse more than 50% of the patients are not utilizing the aerosol efficiently. It has been tried to solve the problem by inserting various spacers or spacing tubes between the aerosol container and the mouth of the patient. The velocity of the particles are reduced within such spacers to such an extent that the patient may inhale the particles more easily. This solution involves the problem that the

aerosol container with the spacer is so bulky that the patient cannot always bring it with him/her.

In another manner for making the medical product particles respirable a powder inhaler with a powdered medical product is used. Such powdered product tends to lump together and form rather big particles with a diameter of several hundred μm . The various known powder inhalers vary with respect to the manner in which the correct amount of the medical product is metered. Thus, in some inhaler packings or capsules in which metered amounts of the medical product is packed separately are used. In other powder inhalers quite different principles are used, but for all such powder inhalers it is a common feature that the medical product cannot be inhaled by the patient in the form in which the product is present in the inhaler, because the medical product particles are too big. Therefore, the patient has to supply energy to the particles so that each of them is disintegrated in several thousand smaller pieces with a diameter of 1-50 μm . This energy supply to the product particles must come from the inhaling force of the patient. The higher air inhaling rate the patient is able to provide, the more forceful turbulence is created in the powder inhaler, and the more respirable particles are formed. Therefore, fast inhalation gives rise to the formation of many respirable particles, but causes simultaneously that the number of respirable particles reaching the outer branches of the bronchial tubes is reduced, because it is necessary to inhale rather slowly in order to get the particles into the outer branches of the bronchial tubes. Moreover, many asthmatic patients are not able to inhale air with a velocity which is sufficient to disintegrate the medical product particles to such an extent that they become respirable. For the above reasons many patients cannot be given an optimum treatment with inhalation therapy.

An inhaler of the aerosol type is disclosed for example in US patent No. 3,809,084, and powder inhalers are disclosed in for example Swedish patent No. 453,566 and German patent No. 2,440,623. The German patent discloses a powder inhaler, in which the gas flow passage is formed with a restriction or throat, and the product chamber is communicating with the restriction of the gas flow passage

through a capillary tube, whereby the medical product may be drawn into the restriction of the gas flow passage through the capillary tube and may be dispersed in the gas flow without using movable parts.

- 5 The present invention provides an oral inhaler of the above type in which the proportion of respirable particles obtainable is drastically increased.

Thus, the present invention provides an oral inhaler for use in inhaling a powdered or particulate medical product and comprising a
10 chamber for containing the medical product, a gas flow passage defining a restriction or throat, and means defining a connecting passage interconnecting the product chamber and the flow passage at the restriction or adjacent thereto so as to allow product to be drawn into the gas flow passage by ejector effect, and the inhaler accord-
15 ing to the invention is characterized in a pressure gas source communicating with the gas flow passage for briefly providing a superatmospheric pressure in one end of the gas flow passage so as to provide a high velocity gas flow through the restriction or throat.

It has been found that the use of a pressure gas source in combination with a restriction or throat in the gas flow passage gives rise
20 to a drastic increase of the proportion of respirable particles dispersed in the gas or air flow, and the provision of such dispersed respirable particles is not dependent on the ability of the patient to inhale vigorously.

25 The pressure gas source may be of any suitable type, such as a container or can containing pressurized or liquefied gas or air and having a valve for releasing small amounts of air or gas at a superatmospheric pressure. The pressure and the amount of gas released should be sufficient to generate a gas flow through the restriction
30 of the flow passage at such a velocity that product is drawn from the product chamber into the gas flow and that most of the product particles are disintegrated to such an extent that the disintegrated particles become respirable.

If the pressure gas source is a container containing pressurized air, the inhaler will be too bulky to be carried by the patient, and the use of a container containing a liquefied propellant gas, such as Freon, may involve undesirable side effects as explained above.

- 5 Therefore, in a preferred embodiment the pressure gas source comprises a manually operatable pumping device comprising a pumping chamber communicating with the gas flow passage, the volume of the pumping chamber being reducible by operating the pumping device. The pumping chamber may totally or partly be defined by a displaceable or
- 10 deformable wall part which may possibly be moved by means of manually operatable moving means. As an example, the pumping chamber may be formed like a balloon, a bulb, or any other elastically compressible body. Alternatively, the pumping device may comprise a piston pump having a displaceable wall part formed like a piston which is ar-
- 15 ranged within the pumping chamber of the inhaler, and a piston rod connected to the piston and having a free end which extends from the inhaler and is provided with an actuating member. In connection with the said restriction or ejector nozzle, such a pumping device may generate a flow of gas or air, which is sufficient to suck or draw
- 20 the medical product from the product chamber into the gas flow and to disintegrate the product particles to such sizes that they are respirable and may be dispersed in the gas or air being pumped. By using such pumping device the propellant may be atmospheric air, and the use of a special propellant gas, which may have undesired side ef-
- 25 fects for the surroundings as well as for the patient when inhaled, is avoided.

- The amounts of the medical product to be inhaled are normally very small provided that the inhaler is able to disintegrate the powdered or particulate product into particles of which substantially all are
- 30 respirable. If this is the case the dose necessary normally amounts too 25-500 micrograms provided that no filler agents are used. It has been found that by using the inhaler according to the invention, doses of this order and also substantially greater doses may efficiently be sucked from the product chamber into the restriction of
- 35 the gas flow passage and dispersed in the air flow in a respirable condition even though a relatively small air volume is pumped through the gas flow passage by means of the pumping device. Furthermore, it

has been found that the proportion of the medical product which is made respirable when sucked into the gas flow passage is increased when the velocity of the air flowing through the gas flow passage and the restriction thereof is increased. Therefore, it should be aimed at to obtain an air flow at a rather high velocity, such as 200-400 km/hour in the restriction of the gas flow passage during a rather short time period. According to the invention such brief air flow at a high velocity may be obtained when the moving means or the movable wall part of the pumping chamber comprises spring means, which may be prestressed. If the pumping device comprises a piston pump, the piston may, for example, be actuated by a coil spring or another spring device, which may be prestressed when the piston is moved to a retracted position in which the piston may be releasably retained by a locking device. When the piston is released, for example by manually operating the locking device, the prestressed spring may move the piston through a short pumping stroke under the influence of a high spring force.

Alternatively, the deformable wall part may comprise a curved, springy diaphragm-like wall part movable between two stable positions, in which the wall part is convexly and concavely curved, respectively. By moving the springy membrane from one of these stable positions to the other, namely from the convexly curved to the concavely curved position, the volume of the pumping chamber may be reduced rather suddenly due to the fast movement of the membrane, whereby a high velocity air flow of a short time duration is obtained in the gas flow passage, whereby it is obtained that most of the medical product, which is drawn into the gas flow passage becomes respirable.

According to another embodiment, the gas flow passage may be closed by a manually operatable valve arranged between the pumping chamber and the restriction. Thus, when the valve is closed, the pumping device may be operated so as to obtain a suitable superatmospheric pressure within the pumping chamber. The pressurized air within the pumping chamber may then be released through the restriction of the gas flow passage when desired by opening the valve. Consequently, this embodiment of the inhaler will function like a kind of air gun or air pistol, by means of which a high velocity air flow of a short

time duration may be provided through the gas flow passage corresponding to the barrel of the gun or pistol.

Thus, when the inhaler according to the invention is operated a relatively small volume of gas or air is caused to flow through the restriction of the gas flow passage at a relatively high velocity (for example 200-400 km/hour). The low static pressure, which is thereby generated in the restriction, causes that medical product from the product chamber is rapidly sucked into the restriction of the gas flow passage. When the product is moved further through the gas flow passage it will become influenced by the concentrated, high velocity air or gas flow from the restriction giving rise to heavy turbulence, whereby the product particles are disintegrated into respirable particles. Because a relatively small gas or air volume is used for operating the inhaler, the flow emerging from the restriction or throat will soon expand, whereby the flow velocity is rather rapidly reduced to about 0 even when the expansion volume is relatively small. Then the air or gas with the respirable particles dispersed therein may be inhaled in a normal manner. Thus, the vigorous gas or air flow formed in the restriction of the gas flow passage has a double function. Firstly, it should cause suction of medical product from the product chamber into the gas flow passage, and, secondly, it should cause disintegration of the product into respirable particles to an extent which cannot be obtained by conventional inhalers apart from aerosol inhalers in which a propellant gas under a rather high pressure is used.

The product chamber may be adapted to receive a single dose of the medical product, which may be packed in a manner known per se, for example in a blister packing or in a capsule, which must be punctured or opened before use of the medical product. However, in a preferred embodiment the product chamber is in the form of a metering chamber connected or connectable to a product reservoir arranged within the inhaler. The product reservoir may then contain a product supply comprising several doses, and each time the inhaler is to be used medical product may be transferred from the reservoir to the metering chamber in a suitable manner. The metering chamber may have such a size that it contains a suitable dose when filled. The medical pro-

duct may be transferred from the product reservoir to the metering chamber in any suitable manner, for example by means of a mechanism as that disclosed in Swedish patent No. 453,566.

The product reservoir may be connected to the metering chamber
5 through a plurality of small openings, such as the openings defined in a sieve- or grid-like wall part. Particles lumped together in the product reservoir may then to some extent be disintegrated when the product is transferred to the metering chamber.

The restriction of the gas flow passage may open directly into a
10 mouth piece formed on the inhaler. In such case the patient has to put the mouth piece into the mouth prior to operating the inhaler, and the brief air flow provided by means of the pumping device as well as the product particles dispersed therein flow directly into the oral cavity of the patient, where the velocity of the air flow is
15 drastically reduced. The patient may then inhale the medical product dispersed in the oral cavity. Alternatively, the restriction of the gas flow passage may open into one end of a mixing chamber having another end communicating with an inhaling mouth piece. When the inhaler is operated, the velocity of the air flow emerging from the
20 gas flow passage will be reduced to a rather small value within the mixing chamber, so that the mixing chamber is filled or almost filled with the gas or air forced through the restriction of the gas flow passage and by the respirable product particles dispersed therein. The patient may then operate the pumping device or another pressure
25 gas source for providing a gas or air flow with dispersed product particles, and, subsequently, when the gas flow has ceased, the dose of aerosol formed in the mixing chamber may be inhaled therefrom.

Means for creating turbulence in the gas or air flow may be provided in the gas flow passage or in the mixing chamber downstream of the
30 restriction or throat. Such means which may, for example, be helically shaped guiding fins or other turbulence creating means, may partly promote the disintegration of the product into respirable particles and partly promote a uniform distribution of the particles in the air or gas flow.

In order to obtain a sufficiently high velocity of the gas or air flow in the restriction of the air flow passage to form the desired respirable particles, the diameter of the restriction or throat must be relatively small. In a preferred embodiment the diameter of the restriction should be greater than 0.1 mm and smaller than 1 mm, for example 0.7-0.8 mm. The diameter could be 0.1-0.5 mm, for example 0.3-0.4 mm. Normally, the passage connecting the product chamber with the restriction of the gas flow passage should have a diameter which is greater than the diameter of the restriction. Otherwise, the frictional forces influencing the product flowing from the product chamber into the gas flow passage would be too high. Thus, the diameter of the connecting passage preferably exceeds 0.5 mm and is preferably 0.5-1.5 mm, for example about 1 mm.

The invention will now be further described with reference to the drawings, wherein

Fig. 1 is a diagrammatic sectional view showing part of a first embodiment of the inhaler according to the invention,
Fig. 2 is a side view and partially sectional view of a second embodiment of the inhaler according to the invention,
Fig. 3 is a side view and a partially sectional view of a third embodiment of the inhaler according to the invention,
Fig. 4 is a side view and partially sectional view of fourth embodiment of the inhaler according to the invention,
Fig. 5 is a diagrammatic plan view and partially sectional view of a fifth embodiment of the inhaler according to the invention, and
Fig. 6 is a side view and partially sectional view of the embodiment shown in Fig. 5.

All of the embodiments of the inhaler according to the invention shown in the drawings comprise a housing 10 defining a reservoir 11 for a medical product. The reservoir 11 may receive a supply of a powdered or particulate product which may, for example be contained in a perforatable product package, and the reservoir 11 may be connected a metering chamber 14, for example via a plurality of narrow openings or bores 13. The metering chamber 14 is communicating with a mixing chamber 16 via a connecting passage 15. The mixing chamber 16 is connected to a pressure gas source 12 through a gas flow passage

17, which defines a nozzle-like restriction 18 at its one end opening into the mixing chamber 16. The connecting passage 15 opens into the gas flow passage 17 at or immediately adjacent to the restriction 18, so that the ejector effect caused by gas or air flowing through the nozzle-like restriction 18 generates a vacuum within the connecting passage.

The product reservoir 11 may be closed by a releasable lid or cap 19 so that a new supply of product or a new product package may be inserted into the product reservoir 11 from time to time. The product package may be perforated or opened before it is inserted into the reservoir. Alternatively, cutting or puncturing means (not shown) may be arranged in the reservoir for automatically opening the product passage when it is inserted. It is also possible - but less convenient - to pour the powdered product into the product reservoir from a larger supply container.

The housing 10 is preferably made from metal and/or plastic, but may be made from any other suitable material. Depending on the material and the shape chosen, the housing may be made as a unitary body or be composed by two or more separately manufactured parts. The housing has a mouth piece 20 which is adapted to be put between the lips of a patient when the inhaler is used. In the embodiment shown in Fig. 1 the pressure gas source comprises a piston pump in which the gas flow passage 17 defines a continuation of the pump cylinder 21 in which a piston 22 is arranged so as to be displaceable therein. The piston 22 is connected to a piston rod 23 which may be connected to an actuating member or an actuating mechanism by means of which a fast forward movement may be imparted to the piston. The piston may be returned to its retracted starting position by means of a return spring or another return means, not shown.

When the inhaler is to be used it is positioned with the mouth piece 20 in an upward direction. Powdered medical product may then flow from the product reservoir 11 through the openings or bores 13 into the metering chamber 14 so as to fill the same. The wall part in which the narrow openings or bores 13 are defined may be sieve- or grid-like so that only particles not exceeding a certain size may be

passed into the metering chamber. Now, by operating the actuating member connected to the piston rod 23 the user may move the piston 12 towards the restriction 18 to obtain a short, quick pressure stroke. This action generates such a superatmospheric pressure within the pumping cylinder that a vigorous air flow, which is directed towards the mouth piece 20, is created with the gas flow passage 17. Within the restriction 18, where the cross section of the gas flow passage 17 is rather small, for example with a diameter of 0.1-0.5 mm, the velocity of the air flow will be rather high, for example 200-400 km/hour. This creates a rather low sub-atmospheric static pressure within the restriction. Because the connecting passage 15 opens into the restriction, the vacuum generated therein causes powdered product to be drawn from the metering chamber 14 and into the air flow through the restriction 18. The high velocity of the air flow and the vigorous turbulence created thereby cause that almost all of the product is disintegrated into respirable particles. The suction of powdered product from the metering chamber 14 into the restriction 18 is made possible by a venting passage 24 in the housing 10 communicating the ambient atmosphere with the metering chamber. Thus, the vacuum generated in the restriction 18 causes air to flow from the ambient atmosphere through the venting passage 24, the metering chamber 14, the connecting passage 15 and into the restriction 18, whereby product from the metering chamber 14 is entrained with the air flow and introduced into the restriction 18. Simultaneously with or immediately after the operation of the pumping device, the patient may insert the mouth piece 20 between the lips and inhale the air and the respirable medical product particles dispersed therein from the mixing chamber 16. Turbulence generating means, not shown, for improving disintegration of the medical product particles may be positioned between the restriction 18 and the mixing chamber 16.

In the embodiment shown in Fig. 2 the pressure gas source 12 is also in the form of a piston pump, but in this case the axis of the pumping cylinder 21 extends transversely to the longitudinal axis of the inhaler. The free end of the piston rod 23 is pivotally connected to one end of an operating member 25 formed like a lever of second order, and the other end of the operating member is pivotally connected to the housing by means of a hinge connection 26. A spring 27

surrounding the free end of the piston rod 23 is adapted to move the piston through its suction stroke.

Adjacent to the mouth piece 20 the mixing chamber 16 comprises an enlargement 29, which may serve as a reservoir for the medical particles, which have been drawn out from the metering chamber 14 and are dispersed in air by operation of the inhaler.

The inhaler shown in Fig. 2 functions in substantially the same manner as described above in connection with Fig. 1. The enlargement 29 may have such a size that substantially all of the dispersion of air and medical particles formed by operation of the inhaler remains in the mixing chamber 16 and its enlargement 29. That means that the patient need not inhale until the medical product has been dispersed by operating the operating member 25. During inhalation, replacement air may flow into the mixing chamber 16, 29 via bores, now shown, extending through the wall of the mixing chamber, whereby the inner space of the mixing chamber is in communication with the atmosphere. The mouth piece may be protected by a removable lid or casing 30 when the inhaler is not in use.

In the embodiment shown in Fig. 3, the pressure gas source 12 also comprises a piston pump with a pumping cylinder 21 having a movable piston therein mounted on a piston rod 23. The opposite end of the piston rod is connected to a cap-shaped member 31 surrounding one end of the housing 10, and the piston rod 23 is surrounded by a coil spring 32 functioning as a tension spring and serving for biasing the piston 22 towards a retracted position. However, the piston may be retained in an advanced position shown in Fig. 3 by means of a locking member 33. The locking member 33 is surrounded by a spring 34 for moving the inner end of the locking member 33 into the piston path. A valve member is mounted in the gas flow passage 17 and is biased towards a closed position by a spring 36, in which position the connection between the pump cylinder 21 and the throat 18 of the gas flow passage is tightly closed. The valve member 35 may, however, be moved to an open position by means of an operating member 36, which is shaped like a lever of first order and mounted in a recess 37 of the housing wall. The operating member 36 is moved to the open

position towards the bias of the spring 34. When the inhaler shown in Fig. 3 is to be used the metering chamber 14 is filled with medical product from the reservoir 11 in a manner described above. The piston 22 is in its retracted position, in which it is out of engagement with the locking member 33 and in which the return spring 32 is unstressed. The valve member 35 is in its closed position. Now, the user may apply an inwardly directed pressure to the cap-shaped member 31, whereby the piston 22 is moved inwardly in the cylinder 21 so as to compress the amount of air trapped within the cylinder. A cam surface formed at the free end of the locking member 33 may during the forward movement of the piston 22 cooperate with a corresponding surface at the front side of the piston so as to move the locking member 33 from the path of the piston towards the bias of the spring 34. When the piston has passed the locking member 33 it is returned to a position in which it extends into the path of the piston behind the piston under the bias of the spring 34. Thus, the piston 22 is locked in its advanced position. The user may now place the mouth piece 20 between the lips and move the valve member 35 to its open position by operating the operating member 36. This means that the compressed air within the cylinder 21 suddenly expands through the gas flow passage 17 and its restriction 18 so that an air flow at a high velocity is provided during a short time period. Medical product from the metering chamber 14 will then be sucked into the restriction 18 and dispersed in the air flow as explained above. When the patient has inhaled the amount of air having the respirable medical particles dispersed therein, the piston 22 may be released by withdrawing the locking member 33 from the path of the piston. The spring 32 will now move the piston 22 and the cap-shaped member 31 to a retracted position, whereby a new amount of air 21 is sucked into the cylinder 21, because the valve member 35 is retained in its open position. When the operating member 36 is released and the valve member 35 has been returned to its closed position, the operation of the inhaler described above may be repeated. In the inhaler shown in Fig. 3 a high velocity air flow of a short duration is provided through the gas flow passage 17 in a manner similar to the operation of an air gun or an air pistol.

In the embodiment shown in Fig. 4 the inhaler comprises a metering mechanism having a rotatable drum or disc 38 with an annular arrangement of metering chambers 14. When the drum 38 is rotated, the metering chambers 14 are successively positioned opposite to the product reservoir 11 and the connecting passage 15, respectively. This metering mechanism may be of a type similar to that described in Swedish patent No. 453,566.

In Fig. 4, the pressure gas source 12 comprises a pumping chamber 39 partly defined by a concave arched depression at one end of the housing 10 and partly by a springy diaphragm or membrane 40 which is convexly domed in its unstressed condition. This spring membrane may be moved between its convexly domed position shown in Fig. 4 and a concavely arched position in which the membrane is substantially in abutting engagement with the arched wall surface of the housing 10 as indicated in broken lines in Fig. 4. The spring membrane 40 may be provided with a centrally arranged pressure button 41.

When the inhaler shown in Fig. 4 is to be used, the protecting cap 30 is unscrewed from the housing 10, and it should be ascertained that the drum 38 has been moved to a position in which a metering chamber filled with medical product is in communication with the connecting passage 15. Thereafter, a pressure force is applied to the button 41 by a finger so as to rapidly move the spring membrane 40 from the position shown in solid lines to the position shown in broken lines in Fig. 4. This means that a high velocity air flow of short duration is generated in the gas flow passage 17 and in its restriction 18, whereby medical product is drawn from the metering chamber 14 into the restriction 18 through the connecting passage 15 as previously explained, and the product sucked into the restriction is dispersed in the air contained in the mixing chamber 16. The patient may now inhale the air and the respirable medical particles dispersed therein from the mixing chamber 16. The spring membrane 40 is now moved back to its convexly domed position shown in solid lines in Fig. 4 and the drum 38 is advanced by one step. Thereafter, the inhaler is again ready for use.

The embodiment of the inhaler shown in Figs. 5 and 6 are of a generally flat shape, and the pressure gas source comprises a piston pump with a piston 12 having a relatively large diameter and a pumping cylinder with a relatively short axial length. The piston may be operated by means of an integral pressure button extending outwardly from the housing 10, and a return spring member 43 is arranged within the pumping cylinder. The gas flow passage 17 comprises a narrow bore forming the restriction 18 opening into a wider end portion 44, which communicates with the mixing chamber 16 through a plurality of transverse discharge openings 45. A wall or projection 46 arranged at the end of the wider portion 44 of the gas flow passage extends transversely from a side wall of the housing so that the mixing chamber 16 communicates with the opening of the mouth piece through a passage 47 defined between the free edge of the projection 46 and the housing wall. Replacement air may flow into the mixing chamber 16 through venting openings 48.

It should be understood that various amendments and modifications of the embodiments shown in the drawings could be made within the scope of the present invention. As an example, the piston pump shown in Fig. 3 may be replaced by a pumping device with a pumping chamber defined by elastically deformable wall parts. Thus, the pumping chamber may be formed like a rubber bulb or a balloon provided with one-way valves.

In the embodiments shown in Figs. 2, 5 and 6, the piston pump 21, 22 may, for example, be replaced by a pumping chamber defined by a spring membrane 40 as that shown in Fig. 4. This spring membrane may be operated by the lever-like operating member 25, whereby the necessary operating pressure may be substantially reduced. The operating member 25 may possibly be adapted to deform the spring membrane to such an extent only that it automatically moves back to its starting position when the operating member is released. Alternatively, the operating member for operating the spring membrane 40 may be shaped like a cap corresponding to the cap 31 shown in Fig. 3 and connected to the housing 10 by screw threads having a large pitch. The spring membrane 40 may then be operated by rotating such cap. The embodiments shown in Figs. 1-3 may be provided with metering mechanisms

similar to that disclosed in the previously mentioned Swedish patent No. 453,566 and that indicated and described in connection with Fig. 4. Generally, the pressure gas source 12 may comprise any device by means of which a high velocity air or gas flow of short duration may
5 be provided in the gas flow passage 17.

EXAMPLE

In an inhaler of the type shown in Figs. 5 and 6 the outer diameter of the piston 22 is 50 mm and the piston stroke is 6-10 mm. This means that for each operation of the piston of the inhaler a volume
10 of 10-20 ml air is compressed rather suddenly and discharged through the gas flow passage 17. The gas flow passage 17 has a minimum diameter of 0.7 mm, and the connecting passage 15 is a bore with a diameter of about 1 mm. By depressing the piston 22, a powdered product contained in the product chamber 14 may be drawn into and dispersed
15 in the air flow through the passage 17 substantially as respirable particles.

CLAIMS

1. An oral inhaler for use in inhaling a powdered or particulate medical product and comprising:
 - a chamber (14) for containing the medical product,
 - 5 a gas flow passage (17) defining a restriction or throat (8), and
 - means defining a connecting passage (15) interconnecting the product chamber (14) and the flow passage at the restriction or adjacent thereto so as to allow product to be drawn into the gas flow
 - 10 passage by ejector effect,
 - characterized in a pressure gas source (12) communicating with the gas flow passage (17) for briefly providing a superatmospheric pressure in one end of the gas flow passage so as to provide a high velocity gas flow through the restriction or throat (18).
- 15 2. An inhaler according to claim 1,
characterized in that the pressure gas source (12) is a manually operatable pumping device (21-23) comprising a pumping chamber (21) communicating with the gas flow passage (17), the volume of the pumping chamber being reducible by operating the pumping
- 20 device.
3. An inhaler according to claim 2,
characterized in that the pumping chamber (21) is totally or partly defined by a displaceable (22) or deformable (40) wall part.
- 25 4. An inhaler according to claim 3,
characterized in manually operatable means (25, 31, 41) for moving said wall part (40).
5. An inhaler according to claim 3 or 4,
characterized in that the moving means or the movable
- 30 wall part of the pumping chamber comprises spring means, which may be prestressed.
6. An inhaler according to claim 5,

c h a r a c t e r i z e d in that the deformable wall part comprises a curved, springy diaphragm-like wall part (40) movable between two stable positions, in which the wall part is convexly and concavely curved, respectively.

- 5 7.. An inhaler according to claim 3 or 4,
c h a r a c t e r i z e d in a manually operatable valve (34-36)
arranged between the pumping chamber (21) and the restriction (18)
for closing the gas flow passage (17).
8. An inhaler according to any of the claims 1-7,
10 c h a r a c t e r i z e d in that the product chamber is a metering
chamber (14) connected or connectable to a product reservoir arranged
within the inhaler.
9. An inhaler according to claim 8,
c h a r a c t e r i z e d in that the metering chamber (14) is
15 connected or connectable to the product reservoir (11) via openings
in a sieve- or grid-like wall part.
10. An inhaler according to any of the claims 1-9,
c h a r a c t e r i z e d in that the restriction (18) of the gas
flow passage (17) opens into one end of a mixing chamber (16, 29),
20 the other end of which is connected to a mouth piece (20).
11. An inhaler according to any of the claims 1-10,
c h a r a c t e r i z e d in that the diameter of the restriction
(18) of the gas flow passage is 0.1-1 mm and preferably 0.7-0.8 mm.

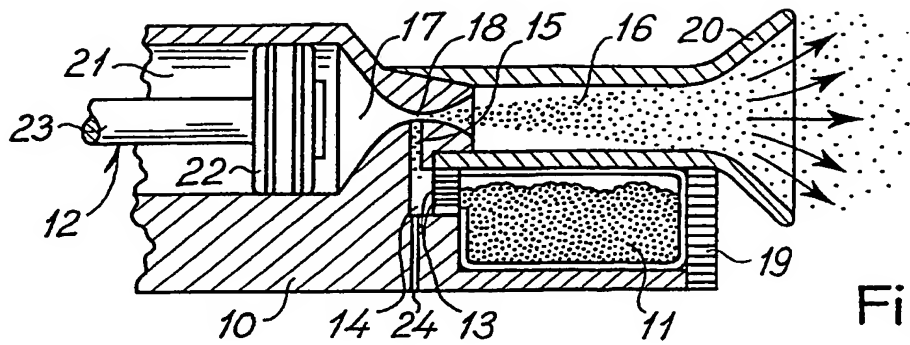


Fig. 1

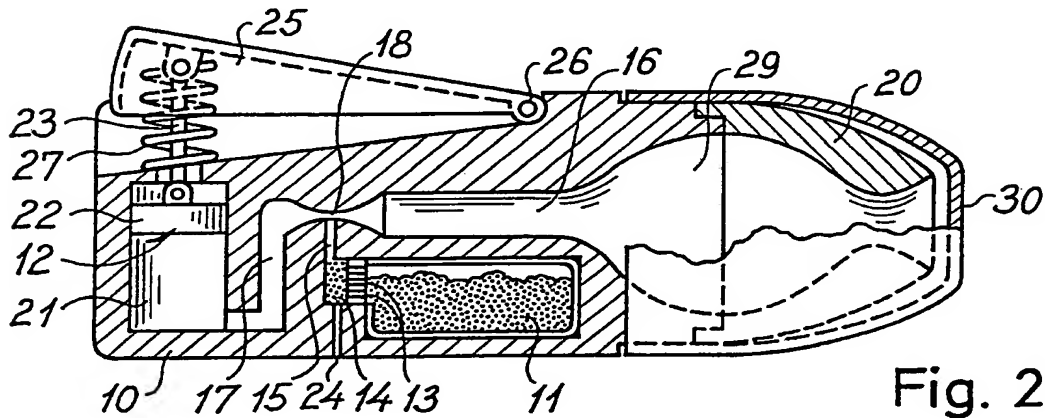


Fig. 2

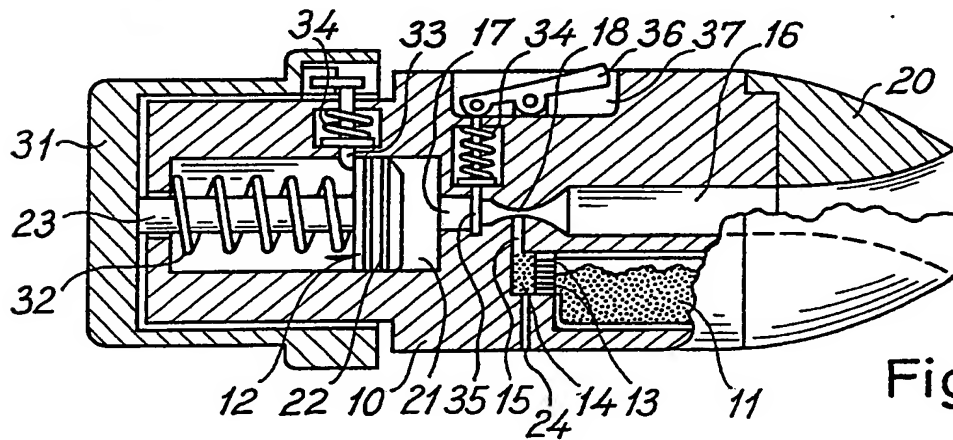


Fig. 3

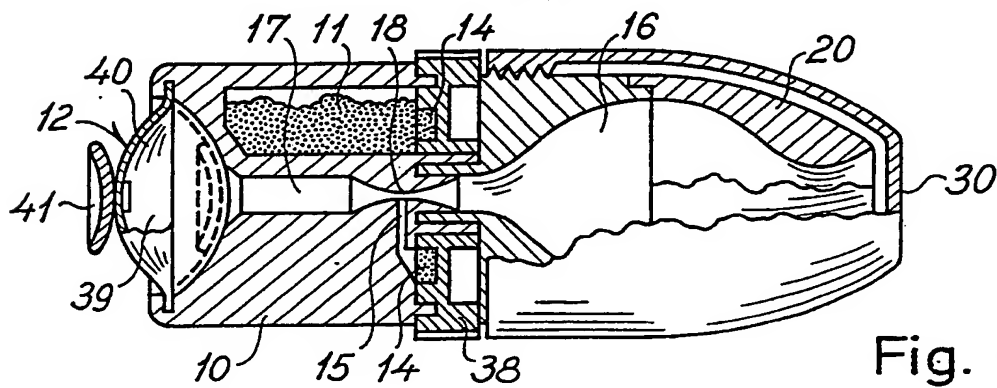
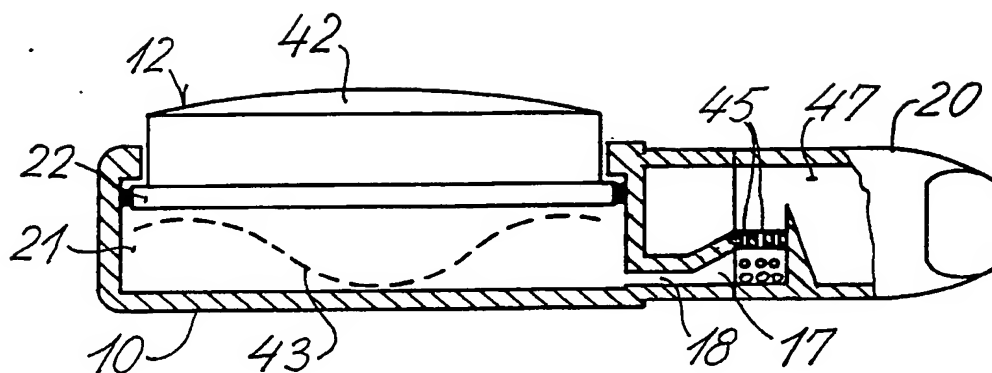
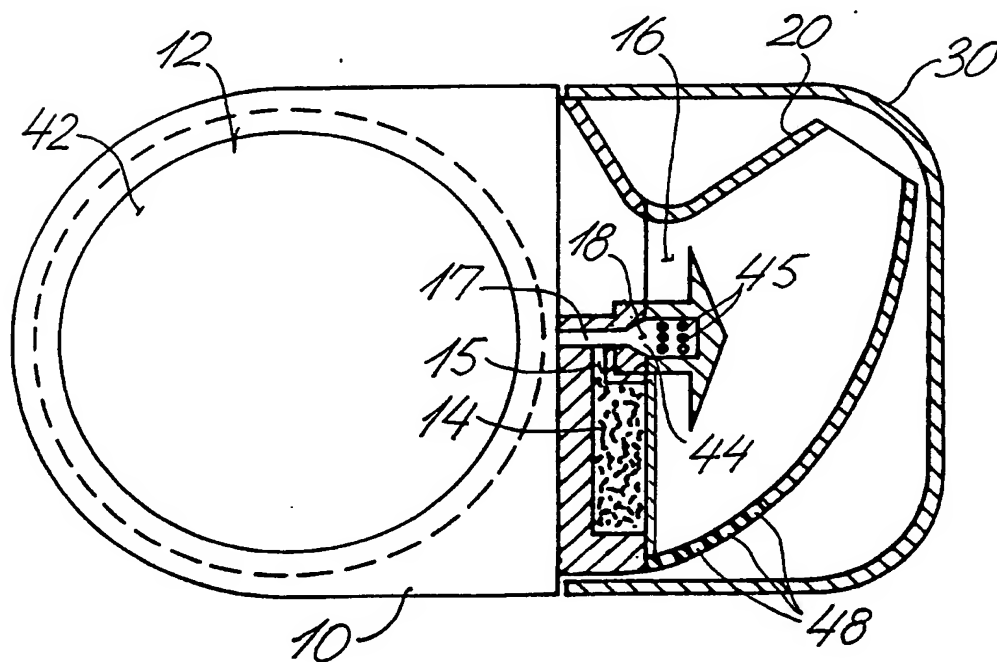


Fig. 4

2/2

**Fig. 5****Fig. 6**

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 90/00005

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC5: A 61 M 13/00, 15/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System *	Classification Symbols	
IPC5	A 61 M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ** with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	DE, C, 471490 (RUDOLF LEX ET AL) 12 August 1931, see the whole document --	1-4,6,8
X	US, A, 4046146 (ROSSKAMP ET AL) 6 September 1977, see column 7, line 11 - line 17 --	1,8- 11
A	DK, C, 79234 (CARL FRANZ FERSTER) 9 May 1955, see the whole document --	
A	DE, B, 1147354 (PAUL RITZAU) 18 April 1963, see the whole document --	
<p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
10th April 1990	1990 -04- 12	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	Leif Karnsäter <i>Leif Karnsäter</i>	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	GB, A, 636854 (THOMAS JAMES CHALMERS MACDONALD) 10 May 1950, see the whole document --	
A	Derwent's abstract, No. 84- 92 820/15, SU 992 069, publ. week 8415 (TARTU UNIV) --	
A	US, A, 4200099 (GUENZEL ET AL) 29 Apr 11 1980, see the whole document -- -----	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 90/00005**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-C- 471490	31-08-12	NONE	
US-A- 4046146	77-09-06	AU-B- 504474	79-10-18
		AU-D- 8411075	77-02-24
		BE-A- 832678	76-02-23
		CA-A- 1059855	79-08-07
		CH-A- 602124	78-07-31
		DE-A-C- 2440623	76-03-04
		FR-A-B- 2282279	76-03-19
		GB-A- 1526303	78-09-27
		JP-A- 51049594	76-04-28
		LU-A- 73228	76-03-02
		NL-A- 7509942	76-02-24
		SE-B-C- 428426	83-07-04
		SE-A- 7509342	76-02-23
		US-A- 4240418	80-12-23
		AT-B- 375018	84-06-25
		DE-A-C- 2524902	76-12-16
		SE-A- 7509343	76-12-03
		DE-A- 2529522	77-01-27
DK-C- 79234	55-05-09	NONE	
DE-B- 1147354	63-04-18	NONE	
GB-A- 636854	50-05-10	NONE	
US-A- 4200099	80-04-29	AU-B- 516852	81-06-25
		AU-D- 3474278	79-10-11
		BE-A- 865806	78-10-09
		CA-A- 1131523	82-09-14
		CH-A- 632673	82-10-29
		DE-A-C- 2716323	78-10-19
		FR-A-B- 2386313	78-11-03
		GB-A- 1603186	81-11-18
		JP-A- 53146494	78-12-20
		LU-A- 79378	78-09-18
		NL-A- 7803544	78-10-10
		SE-A- 7803898	78-10-08

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.